BOARDS AND COMMISSIONS
Board of Pharmacy
(New Administrative Regulation)

201 KAR 2:440. Legend drug repository.

RELATES TO: 315.191, 315.450, 315.452, 315.454, 315.456, 315.458, 315.460
STATUTORY AUTHORITY: 315.191, 315.458
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.458 requires the board to promulgate regulations to establish the legend drug repository program. This administrative regulation establishes the legend drug repository program and the requirements to participate in the program.

Section 1. Definitions. (1) “Authorized recipient” means a recipient that has received authorization from the board to participate in the legend drug repository program pursuant to Section 2 and whose authorization has not been revoked by the board pursuant to Section 3.

(2) “Board” means the Kentucky Board of Pharmacy.

(3) “Controlled substance” has the same meaning as defined in KRS 218A.010.

(4) “Dispense” has the same meaning as defined in KRS 315.010.

(5) “Distribute” has the same meaning as defined in KRS 315.400.

(6) “Donor” shall mean any entity legally authorized and permitted to possess drugs, including but not limited to a wholesaler or distributor, third party logistic provider, pharmacy, clinic, surgical or health center, detention and rehabilitation center, laboratory, medical or pharmacy school, prescriber or other health care provider, or health facility. Donor shall also mean government agencies and entitles that are federally authorized to possess drugs including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, FDA authorized importers such as those under Federal FD&C Section 801, 804, or similar provisions, and prisons.

(7) “Drug” has the same meaning as defined in KRS 315.010.

(8) “Eligible patient” means an individual who is indigent, uninsured or underinsured. Other patients shall be considered eligible if a need for the donated drugs is not identified among indigent, uninsured and underinsured individuals.

(9) “Health care provider” has the same meaning as in KRS 304.17A-005.

(10) “Heath facility” has the same meaning as in KRS 216B.015.

(11) “Original packaging” shall mean the packaging in which the drug was donated by the donor.

(12) “Pharmacist” has the same meaning as defined in KRS 315.010.

(13) “Recipient” means a pharmacy as defined by KRS 315.010.

(14) “Relabeler” has the same meaning as defined in 201 KAR 2:320.

(15) “Repackager” has the same meaning as defined in KRS 315.400.

(16) “Returns processor” shall have the same meaning as in 21 U.S.C. Section 360eee(18) and shall include but is not limited to a reverse distributor.

(17) “Unopened tamper-evident packaging” shall have the same meaning as United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose, multiple dose, immediate, secondary, and tertiary packaging.

Section 2. Participation in the Legend Repository Program. (1) Donors may donate drugs to

an authorized recipient. An authorized recipient may receive donated drugs from donors. Prior to the first donation from a new donor, an authorized recipient must verify and record the following:

(a) The donor meets the definition provided in Section 1;

(b) The donor's name, address, phone number, and permit number;

(c) The donor will only make donations of drugs in accordance with Section 3;

(d) If applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient.

(2) Any recipient seeking to become an authorized recipient in the program shall complete and provide to the Board the Legend Drug Repository Authorized Recipient Form that includes the specific policies and procedures of the recipient for planned implementation of the repository program. The policies and procedures shall include drug acceptance, destruction or transfer for unauthorized unaccepted drugs, quarantine of donated drugs, the electronic or written maintenance of inventory, storage and maintenance of donated drugs, recordkeeping of dispensed drugs and patient eligibility affidavit forms, separation of donated drugs and repackaging of donated drugs.

(3) The board may revoke the authorization of a recipient to participate in the program by issuing a written notice to the recipient. Such revocation shall include references to the specific requirements that were violated and the corrective actions necessary for the recipient to resume its participation in the program.

(4) Nothing in this chapter shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established by this section.

(5) A drug manufacturer, repackager, or wholesaler other than a returns processor participating in this program shall comply with the requirements of 21 U.S.C. Sections 360-1 through 360-4 relating to drug supply chain security.

Section 3. Accepting, Inspecting, and Storing Drugs. (1) An authorized recipient may only accept into inventory donated drugs that:

(a) Are in original, unopened, sealed, and tamper-evident packaging; or have been repackaged under this program in accordance with Section 4.4;

(b) If in a single unit dose, the packaging of that dose must be unopened;

(c) Are not classified as a controlled substance;

(d) Are not visually adulterated or misbranded;

(e) Are not samples;

(f) Have an expiration date of ninety days or greater;

(g) Have packaging that lists the lot number of the drug;

(h) Are not considered to be medical supplies;

(i) Do not require only being dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements; and

(j) Have a USP-recognized method to detect improper temperature variations if the drugs require temperature control other than "room temperature storage."

(2) Donated drugs that do not meet the requirements of Section 3.1 must be disposed by returning it to the drug donor, destroying it by incinerator, medical waste hauler, or other lawful method, or transferring it to a return processor. A record of disposed drugs shall consist of the disposal method as described above, the date of the disposal, and the name, strength, and quantity of each drug disposed. No other record of disposal shall be required.

(3) All drugs received but not yet accepted into repository inventory shall be quarantined in a separate, designated area.

(4) Prior to or upon accepting a donation or transfer into inventory, an authorized recipient shall maintain a written or electronic inventory of the donation, consisting of the name, strength, and quantity of each accepted drug, and the name address, phone number, and permit number, if applicable, of the donor. This record shall not be required if the two parties are under common ownership. No other record of donation shall be required.

(5) An authorized recipient shall store and maintain donated drugs physically separated from other non-donated inventory and in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and USP standards.

Section 4. Safe Distribution and Dispensing of Drugs. (1) Notwithstanding any other law or rule, an authorized recipient may:

(a) Distribute donated drugs to another authorized recipient or to an entity participating in a drug donation program operated by another state.

(b) Repackage donated drugs as necessary for storage, dispensing, administration, or distribution in accordance with Section 4.4.

(c) Replenish drugs of the same drug name and strength previously dispensed or administered to eligible patients in accordance with 21 U.S.C. 340B.

(2) An authorized recipient may only administer or dispense drugs that:

(a) Meet the requirements of Section 3.1, including not being visually adulterated or misbranded, as determined by a pharmacist employed by, or under contract, with the health facility or pharmacy;

(b) Are, if dispensed to a patient, repackaged into a new container or have all previous patient information on the donated container redacted or removed;

(c) Are properly labeled in accordance with KRS 217.816;

(d) Have an expiration date that will not expire before the full use by the patient based on the prescribing practitioner's directions for use; and

(e) Are prescribed by a physician, advanced registered nurse or a physician assistant and dispensed by a pharmacist KRS 315.454(1)(d).

(3) An authorized recipient may dispense or administer drugs to an eligible patient only if otherwise permitted by law. Prescription drugs may only be dispensed or administered to patients pursuant to a valid prescription drug order and shall have patient-specific written or electronic records maintained in accordance with KRS Chapter 315 and 201 KAR Chapter 2.

(4) Repackaged drugs shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a pharmacist. If multiple packaged donated drugs with varied expiration dates are repackaged together, the shortest expiration date shall be used.

(5) The donation, distribution, transfer, receipt, or facilitation of donations, distribution, transfers, and receipt of drugs pursuant to this chapter shall not be considered wholesale distribution and shall not require licensing as a wholesale distributor.

(6) An entity participating in a drug donation or repository program operated by another state may participate in this program, and in the case of a pharmacy, may dispense donated drugs to residents of this state. This entity is required to comply with all laws and rules in this state.

(7) Indigent and uninsured patients shall have priority access to drugs dispensed through the repository program. If a drug is available and no indigent or uninsured patient requests dispensing of the drug, the drug shall be made available to underinsured patients before dispensing to others. All authorized recipients shall use the Patient Eligibility Affidavit Form provided by the board when confirming a patient's status as indigent, uninsured, underinsured or other.

(8) No legend drug or supply needed to administer a legend drug that are donated for use under this program may be resold.

(9) All legend drugs, with the exception of controlled substances and extemporaneously compounded drugs, are eligible for dispensing under this program.

(10) No handling fee shall be charged to a patient for pharmacy dispensing of a repository drug.

Section 5. Forms and Recordkeeping. (1) All records required by this chapter shall be retained in physical or electronic format, on or off the authorized recipient's premise for a period of five (5) years. A donor or authorized recipient may contract with one another or a third-party to create and/or maintain records on each other's behalf. An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to this chapter if it allows for such information to be readily retrievable. Upon request by the board, the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

(2) An entity which chooses to participate in the program shall make all records available to audit by the board within forty-eight (48) hours.

(3) When performing any action associated with this program or otherwise processing donated drugs for tax, manufacturer, or other credit, an authorized recipient is considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns under federal law.

(4) A donation, or other transfer of possession or control, shall not be construed as a change of ownership unless it is specified as such by the authorized recipient. If a record of the donation's transaction information or history is required, the history shall begin with the donor of the drugs, shall include all prior donations, and, if the drugs were previously dispensed, shall only include drug information required to be on the patient label in accordance with KRS Chapter 315 and 201 KAR Chapter 2.

Section 6. Authority. This chapter shall have sole authority over the program and shall supersede any inconsistent law or rule.

Section 7. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "USP 659 Packaging and Storage Requirements," 05/2017;

(b) "Legend Drug Repository Authorized Recipient Form," Form Rep. 1121A (12/2021);

(c) "Legend Drug Repository Patient Eligibility Affidavit Form," Form Rep. 1121B (12/2021).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVED BY AGENCY: December 14, 2021

FILED WITH LRC: December 14, 2021 at 12:49 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 23, 2022 at 9:00 a.m. Eastern Time via zoom teleconference with a physical location of the KentuckyBoard of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort,Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. Ifyou do not

wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through February 28, 2022. Send written notification of intent to be heard at the public hearing orwritten comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) What this administrative regulation does:

(a) This administrative regulation establishes the legend drug repository program for pharmacies within the Commonwealth and sets requirements relating to the ability for a pharmacy to accept drugs as partof the legend drug repository program.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations.Moreover, KRS 315.482 directs the Board to create by administrative regulation a legend drug repository program.

(c) How this administrative regulation conforms to the content of the authorizingstatues: This administrative regulation establishes the legend drug repositoryprogram and sets forth requirements relating to requirements of the legend drug repository program.

(d) How this administrative regulation currently assists or will assist in the effectiveadministration of the statutes: The administration regulation will ensure the intent of the legislature is followedand the legend drug repository program is created. .

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Notapplicable. This is a new regulation.

(b) The necessity of the amendment to this administrative regulation:Not applicable. This is a new regulation.

(c) How the amendment conforms to the content of the authorizing statutes:Not applicable. This is a new regulation.

(d) How the amendment will assist in the effective administration of the statutes:Not applicable. This is a new regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies will be affected by this amendment, butparticipation in the legend drug repository program is completely optional.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it isan amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) willhave to take to comply with this administrative regulation or amendment: Pharmacies will have to familiarize themselves with amended language and ensure they follow the requirements if they choose to participate in the legend drugrepository program.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

This regulation will ensure that the patients of pharmacies are provided with free medication in the case that a pharmacy participates in the program and patients meet the eligibility requirements. For pharmacies, this ensures drugs are not wasted.

(5) Provide an estimate of how much it will cost to implement this administrativeRegulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcementof this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly orindirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase anyfees.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all pharmacies equally thatchoose to participate in the program.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties,fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be the only entity impacted by this administrativeregulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizesthe action taken by the administrative regulation. KRS 315.191(1)(a) and KRS 315.458.

(3) Estimate the effect of this administrative regulation on the expenditures and revenuesof a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or localgovernment (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the Board in subsequent years.

(c) How much will it cost to administer this program for the first year?No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years?No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explainthe fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: